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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,193	07/18/2003	Brad S. Culbert	TRIAGE.021A	2665

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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3775

NOTIFICATION DATE	DELIVERY MODE
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10/30/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/623,193	Applicant(s) CULBERT ET AL.	
	Examiner Anu Ramana	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-27,33-41 and 43-72 is/are pending in the application.
- 4a) Of the above claim(s) 24-25 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,23,26,33-41,43,44,46,50-59 and 61-72 is/are rejected.
- 7) ☒ Claim(s) 45,47-49 and 60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/30/08 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/30/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18, 23, 26, 33-41 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 18, the limitation “through a native facet of a first vertebra” is deemed to be new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 23, 26, 33-41 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 18, the limitation, “through a native facet of a first vertebra” renders the claim vague and indefinite. It is unclear what Applicant means by the term “native facet.”

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 23, 33-41, 43-44, 46, 50-59 and 61-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray (US 5,527,312) in view of Pepper et al. (US 5,989,255).

Ray discloses a method of providing spinal fixation including the steps of: providing a fixation device 40 and a screw 30 wherein the screw is advanced through a first vertebra and into the pedicle of a second vertebra (Fig. 1, col. 2, lines 26-67 and col. 3, lines 1-47).

Ray discloses all elements of the claimed invention except for: a fixation member having a proximal anchor with a slip ring that is advanced distally over retention structures on the body of the fixation member and wherein a second portion of the fixation member is separated and removed from the first portion of the fixation member after the proximal anchor is advanced distally along the fixation device.

Pepper et al. teach a screw including: a first portion 18 that forms a bone anchor; a second portion 13A that forms a proximal end; and wherein the first and second portions are detachably coupled to one another at a junction, i.e., the plane along which second portion 13A is separated from the first portion; and a proximal anchor including a washer or "slip ring" 26 that is advanced distally over retention structures on the body of the screw (Figs. 1-3, col. 3, lines 66-67, cols. 4 and 5).

Regarding claims 34 and 64, Pepper et al. teach a proximal portion having flats 19 and 20 that engage a drill chuck 21.

Regarding claims 39-41, 54-56 and 69-71, it is noted that the length of the fixation device used is a function of the thickness of the underlying bone tissue.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the bone screw of Ray with the screw as, for example, taught by Pepper et al. wherein so doing would amount to mere substitution of one functionally equivalent fixation device for another within the same art and the selection of any of these fixation devices would work equally well in the Ray device.

The claimed method steps are rendered obvious by the above discussion.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on July 30, 2008 have been considered but are not persuasive for the following reason.

It is the Examiner's position that Ray discloses advancing a bone anchor through the facet joint into the base of a transverse process of a vertebra (Fig. 1 and col. 1, lines 52-63). The insertion step disclosed by Ray requires at least a portion of the bone anchor to be situated within the pedicle of a vertebra. Further, the use of the transitional phrase "comprising" in Applicant's claimed method steps does not preclude additional steps such as a laminectomy. Thus, Applicant's claimed invention is rendered obvious by the combination of Ray and Pepper et al.

Allowable Subject Matter

Claims 45, 47-49 and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
October 26, 2008

/Anu Ramana/
Primary Examiner, Art Unit 3775